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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,586	SATO ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *15-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I claims 1-14 in the reply filed on 11/26/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant further elected cationic and anionic polymers as species elections. Upon further consideration, the Examiner is withdrawing the specie election requirement. Claims 15-36 are withdrawn from consideration as being drawn to non-elected subject matter.

Applicant is correct in that Group III invention includes claims 25-36.

Accordingly, claims 1-14 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanida et al. (US 6,214,378).

Tanida et al. disclose in the abstract (examiner added emphasis):

This invention offers capsules for oral preparation which is useful for colon diseases such as colon cancer, ulcerative colitis, constipation and diarrhea and for systemic diseases such as osteoporosis and which does not undergo any change at all in stomach and in small intestine but firstly start to disintegrate upon arriving at large intestine and, at the same time, quickly release the drug therefrom wherein the capsule base therefor is hydroxypropylmethylcellulose (HPMC) or polyethyleneglycol-compounded HPMC, gelatin or agar and, on the surface of said capsule base in which powder or liquid containing a pharmacologically active substance is encapsulated, a double-coated structure comprising an inner layer consisting of a cationic copolymer and an outer layer consisting of anionic copolymer is formed.

Tanida et al. disclose in claims 1-4, 7 and 8 (examiner added emphasis):

1. A capsule comprising a base layer consisting of hydroxypropylmethylcellulose, a mixture of polyethylene glycol with hydroxypropylmethylcellulose, gelatin or agar, the outside surface of said base layer being successively coated with an inner layer consisting of a cationic copolymer, and an outer layer consisting of an anionic copolymer.

2. The capsule according to claim 1, wherein the cationic copolymer is a copolymer of methyl methacrylate with butyl methacrylate and dimethylaminoethyl methacrylate or polyvinylacetal diethylaminoacetate.

3. The capsule according to claim 1, wherein the anionic copolymer is at least one selected from a group consisting of a copolymer of methacrylic acid with methyl methacrylate, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, carboxymethylethylcellulose and cellulose acetate phthalate.

4. The capsule according to any one of claims 1–3, wherein the cationic copolymer and the anionic copolymer is each in an amount of about 5 mg to about 200 mg.

> **7.** A capsule preparation comprising the capsule according to any one of claims **1–3**, and a pharmacologically active substance encapsulated in the capsule.
>
> **8.** The capsule preparation according to claim **7**, wherein the pharmacologically active substance is at least one selected from a group consisting of polypeptides, anti-inflammatory agents, anti-tumor agents, antibiotics, chemotherapeutic agents, remedies for ulcerative colitis, remedies for irritable colon syndrome, steroidal preparations, vitamins, drugs for constipation, anti-sense drugs and immunosuppressants.

Thus instant claims 1-4 and 13 are anticipated. It is the Examiner's position that, in the absence of evidence to the contrary, since the components taught in the art are the same as instantly claimed then it would have the same disintegration test time and swell and dissolve at the appropriate pH. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

In column 9, lines 35-40, Tanida et al. disclose a core comprising:

Prednisolone	10.0 parts by weight
Lactose	69.0 parts by weight
Crystalline cellulose	10.0 parts by weight
Polyvinylpyrrolide (PVP)	10.0 parts by weight
Magnesium stearate	1.0 parts by weight

Thus claims 7 and 12 are anticipated..

Tanida et al. teach that basic amino acids can be in the core (collumn 2, lines 1-26 and claim 12).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Okayama et al. (US 5,654,004).

Okayama et al. disclose in claims 1-7 (examiner added emphasis):

> What is claimed is:
>
> 1. An oral pharmaceutical preparation releasable in the lower digestive tract, said preparation having a double-coated structure wherein a solid drug having a core containing an active ingredient is covered with both 1) an inner coat made of a cationic polymer which is soluble or swelling at a pH of 6.0 or below and 2) an outer coat made of an anionic polymer which is soluble at a pH of 5.5 or above, said cationic polymer being an aminoalkyl methacrylate copolymer, said anionic polymer being a methacrylic acid copolymer comprising methacrylic acid and methyl methacrylate.
>
> 2. The preparation according to claim 1 wherein said inner coat is applied to said solid drug to a thickness of 10–300 μm.
>
> 3. The preparation according to claim 1 wherein said inner coat is rendered smooth by addition of a plasticizer which is triacetin, a citrate ester or polyethylene glycol and includes a binding inhibitor which is a member selected from the

group consisting of talc, titanium oxide, calcium phosphate, and hydrophobic anhydrous silicic acid.

4. The preparation according to claim 1 wherein said anionic polymer is applied in the amount of 1–40% by weight of said solid drug.

5. The preparation according to claim 1 wherein said drug is ketoprofen or calcitonin, said inner coat is made from dimethylaminoethyl methacrylate and said outer coat is made from 1) a copolymer comprising methacrylic acid and methyl methacrylate; or 2) hydroxy-propylcellulose.

6. The preparation according to claim 1, wherein the core contains a sorbefacient, said sorbefacient being a member selected from the group consisting of sugar esters, sucrose esters of fatty acid, glycyllysinate salts, glycyrrhetic acid, dipotassium glycyrrhizinate, bile acid, glycerol esters of fatty acid, 1-[(2-(decylthio)ethyl]azacyclopentan-2-one, adipic acid, basic amino acids, polyethylene glycol and sodium caprate.

7. The preparation according to claim 1 wherein the active ingredient is a member selected from the group consisting of peptides, proteins, anti-inflammatory agents, antineoplastic agents, antibiotics and chemotherapeutics.

* * * * *

Thus, instant claims 1-4, 7 and 13 are anticipated. It is the Examiner's position that, in the absence of evidence to the contrary, since the components taught in the art are the same as instantly claimed then it would have the same disintegration test time and swell and dissolve at the appropriate pH. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanida et al. (US 6,214,378) in view of with respect to claims 9-11 Adesunloye et al. (US 5,874,106).

Applicant claims a medicinal oral preparation for colon delivery.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Tanida et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Adesunloye et al. teach adding 1-5 wt % amino acids and 0.1 to 1 wt % carboxylic acids, such as citric acid, to capsule fill (Abstract; and claims 1-14).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Tanida et al. is that Tanida et al. do not expressly teach adding 5-20 wt% amino acids and 0.1 to 3 wt% organic acids as pH adjusters. This deficiency in Tanida et al. is cured by the teachings of Adesunloye et al.

2. The difference between the instant application and Tanida et al. is that Tanida et al. do not expressly teach the core having a diameter of 5 to 8 mm and a thickness of 3 to 6 mm.

3. The difference between the instant application and Tanida et al. is that Tanida et al. do not expressly teach the weight of the inner layer relative to the core is 5 to 15 wt% and the weight of the outer layer relative to the core is 5 to 15 wt%.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add amino acids and carboxylic acids, as suggested by Adesunloye, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Tanida et al. Suggest adding other components (column 3, lines 55-56) and suggest adjusting the pH (column 4, lines 10-13). Adesunloye et al. teach common ordinary

amino acids and common ordinary carboxylic acids to add to capsule fill which would by their nature alter the pH.

2 and 3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the core having a diameter of 5 to 8 mm and a thickness of 3 to 6 mm and the weight of the inner layer relative to the core is 5 to 15 wt% and the weight of the outer layer relative to the core is 5 to 15 wt% and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is merely optimization of the components taught by Tanida et al. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Summary: It appears that the instantly claimed medicinal preparation for colon delivery comprising cationic and anionic polymers is taught in the art. Addition of common ordinary amino acids and common ordinary carboxylic acids in capsule fill is also taught in the art.

From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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